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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,477	01/02/2002	Yoshihiro Takai	18721-7053	5209
23639	7590	07/13/2005	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO CENTER 18 FLOOR SAN FRANCISCO, CA 94111-4067			CHURCH, CRAIG E	
			ART UNIT	PAPER NUMBER
			2882	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/037,477	TAKAI ET AL.	
	Examiner	Art Unit	
	Craig E. Church	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-20, 22-28, 34 and 37-49 is/are pending in the application.
- 4a) Of the above claim(s) 22-28 and 42-49 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-20 is/are allowed.
- 6) ☒ Claim(s) 1-10, 34, 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-10, 12-20, 34 and 37-41, drawn to tracking a patient *marker* by x-ray imaging, classified in class 378, subclass 65.
- II. Claims 22-28 and 42-49, drawn to IMRT while tracking patient *movement without a marker*, classified in class 378, subclass 65.

The inventions are distinct, each from the other because:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require tracking while irradiating. The subcombination has separate utility such as IMRT without tracking a marker.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-28 and 42-49 are withdrawn from consideration as being directed to a non-elected invention.

See 37 CFR 1.142(b) and MPEP § 821.03.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112 first paragraph as failing to provide an enabling disclosure. There is no teaching of how to acquire multiple images in a physiological cycle.

Claims 37-41 are rejected under 35 U.S.C. 112 first paragraph for the reasons set forth in the objection to the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7, 9, 10, 34 and 37-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Kunieda et al (6307914). Kunieda teaches a pursuing (tracking) radiation therapy system comprising a therapy x-ray beam generating LINAC 15, patient support couch 20 (called a base), first and second x-ray imaging systems 21a-f and 22a-f, markers 17 indicating tumor location, data processing means 24-32 for receiving data from the imaging systems and determining the dynamic location of the tumor and various controllers for adjusting the therapy apparatus in response to the detected tumor position. Lines 15-28 of column 9 explain such control includes gating source 15 on and off. Line 59 of column 15 to line 11 of column 16 teach that such control includes

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moving the patient couch (base). Lines 14-36 of column 16 mention that such control includes adjusting a multileaf collimator 15a. Lines 59-62 of column 11 reveal that the markers may be of various shapes and may be implanted in the patient. Lines 40-62 of column 16 suggest the use of multiple markers, and lines 36-51 of column 17 describe markers on the exterior surface of the patient which are imaged by TV cameras 1 and 2. Since Kunieda's imaging is of a human patient, it inherently occurs during a physiological cycle (the claims do not recite that the images are acquired during the *same* cycle). Columns 1 and 2 of Kunieda describe tracking a target during radiation therapy using the anatomy of a patient to locate a region to be treated and enabling radiation therapy.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda in view of Cosman (6459769). Kunieda does not suggest use of two beam collimators in series. Cosman discloses radiation therapy apparatus comprising first 12/16 and second 20/24 multileaf collimators, and it would have been obvious to equip the Kunieda device with a second MLC as taught by Cosman to enhance its ability to shape and control the therapy beam.

Claims 12-20 are allowed.

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Applicant's arguments filed March 31, 2005 have been fully considered but they are not persuasive. Applicant's assertions regarding claims 1 and 10 are in error. Lines 59 et seq of column 11 of Kunieda explicitly explain that not only the position of a tumor with respect to a marker is measured but also the torsion and rotation between a patient tumor 17 and marker 18 is detected. See also lines 31-46 of column 12. It must be acknowledged that the goal of Kunieda's invention is precise irradiation of a *tumor* and not of a *marker* which clearly requires that the positional relationship between tumor and marker be known.

Regarding claims 37-39, since Kunieda's imaging is of a human patient, it inherently occurs during physiological movement of the patient, and no means are provided to ensure that images are acquired only during specific phases of a cycle (the claims do not recite that the images are acquired during the *same* cycle). Therefore, Kunieda's images occur during multiple phases as claimed. Lines 14-36 of column 16 mention that control includes adjusting a multileaf collimator 15a.

Regarding claims 34-36, columns 1 and 2 of Kunieda describe tracking a target during radiation therapy using the anatomy of a patient to locate a region to be treated and enabling radiation therapy.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

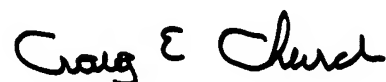
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

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advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Craig E.

Church at telephone number (571) 272-2488.

A handwritten signature in black ink that reads "Craig E Church". The signature is written in a cursive, slightly stylized font.

Craig E. Church  
Senior Examiner  
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